Remarks

Claims 1-20 were pending. Claim 1 is amended herein, claims 3-20 are cancelled, and new claim 21 is added. As a result, claims 1, 2, and 21 are pending. The new and amended claims are supported throughout the originally filed specification and claims. Amended claim 1 is supported, e.g., by originally filed claims 1, 4, 14, and 15, by SEQ ID NO:5, and by paragraphs [0009], [0011], and [0041] of the specification, and by SEQ ID NOS:1 and 4. Paragraph [0009] discloses that the extracellular amino terminal domain is encoded by exons 1-9, as set out in SEQ ID NO:1. It discloses that exon 4 is nucleotides 34575 to 38024 of SEQ ID NO:1. Paragraphs [0011] and [0041] disclose that the amino terminal extension comprises (is encoded by) four genomic exons [exons 1-4 described in paragraph 0009]. A comparison of the sequence of exon 4 (nucleotides 34575-38024 of SEQ ID NO:1) and the cDNA of SEQ ID NO:4 reveals that exon 4 ends at nucleotide 31,485 of SEQ ID NO:4. A comparison of the sequences of exons 1-4 of SEQ ID NO:1, the cDNA sequence of SEQ ID NO:4, and the protein sequence of SEQ ID NO:5 reveals that exons 1-4 encode residues 1-10,427 of SEQ ID NO:5. Claim 21 is supported, e.g., by SEQ ID NO:1 and paragraph [0009]. The element of fragments of SEQ ID NO:5 recognized by an antibody that selectively binds to SEQ ID NO:5 is supported, e.g., by originally filed claim 15, part (d), and claim 14.

The amended abstract is supported by the original abstract.

The amendments to paragraph [0041] are supported by the original paragraph [0041], paragraph [0043], and Table 4.

In reply to the Raw Sequence Listing Error Report that was mailed to the Applicants, an amended sequence listing on two compact disc copies is submitted herewith. In the amended sequence listing, the description of SEQ ID NOS:6 and 7 was changed from "synthetic" to "artificial". That is the only amendment. The amended sequence listing introduces no new matter.

Specification Objections

The Examiner objected to the abstract as exceeding the maximum length of 150 words. The abstract has been amended to make the length less than 150 words, obviating this objection.

The Examiner objected to paragraph [0041] as referring to SEQ ID NO:4 as genomic DNA when paragraphs [0043] and Table 4 refer to it as a cDNA. Paragraph [0041] has been amended to correctly state that SEQ ID NO:4 is a cDNA, obviating this objection.

Priority

The Examiner established priority of claim 1 and 2 from provisional application 60/427,045, filed Nov. 15, 2002. He established a priority date for claim 3 of Nov. 17, 2003. He established a priority date of April 17, 2001, for claim 4. He invited the Applicant to submit evidence of an earlier priority date for claims 1, 2, and 3. Applicant declines at this time to submit evidence of earlier priority than Nov. 15, 2002, for pending claims 1, 2, and 21.

The Rejections of the Claims Under 35 U.S.C. § 112

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. This rejection, insofar as it may apply to the amended claim 1, is respectfully traversed.

The Examiner stated that claim 1 was indefinite without reciting a SEQ ID NO. The claim now recites SEQ ID NO:5, and Applicant believes this obviates the rejection.

Claims 3 and 4 were rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description. This rejection is respectfully traversed.

Claim 3 recited the isolated nucleic acid molecule of claim 2 wherein the sequence has at least about 70% homology with SEQ ID NO:4. Claim 4 recited a fragment of SEQ ID NO:4. Claims 3 and 4 are canceled. Claim 1 recites, "An isolated nucleic acid molecule encoding CA125 (SEQ ID NO:5) or a fragment thereof, wherein the isolated nucleic acid molecule encodes a polypeptide comprising residues 1-10,427 of SEQ ID NO:5 or a fragment of residues 1-10,427 of SEQ ID NO:5 recognized by an antibody that selectively binds to SEQ ID NO:5."

The Examiner stated that claims 3 and 4 encompass a genus of widely varying species of isolated nucleic acid molecules. He quoted the Federal Circuit in *Univ. of*

California v. Eli Lilly and Co., 119 F.3d 1559, 43 U.S.PQ2d 1398 (Fed. Cir. 1997): "A written descrption of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name." *Id* at 1567.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, Fed. Register 66:1099-1111 (Written Description Guidelines) states: "The complete structure of a species of a species or embodiment typically satisfies the requirement that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention. If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. 112, ¶1 , for lack of written description must not be made." The complete structure of "An isolated nucleic acid molecule encoding CA125 (SEQ ID NO:5) or a fragment thereof" is disclosed in the specification and recited in claim 1. The complete structures of genomic nucleic acid sequences encoding SEQ ID NO:5 and fragments thereof are disclosed in the specification in SEQ ID NOS:1-3. The complete structure of a cDNA encoding SEQ ID NO:5 is disclosed as SEQ ID NO:4. The complete structure of any other nucleic acid encoding SEQ ID NO:5 or a a fragment thereof is disclosed by the disclosure of SEQ ID NO:5 in the specification and by the knowledge of the genetic code. The complete and exact structure of every possible species within the genus claimed by claim 1 is disclosed in the specification. Thus, a rejection under the written description requirement "must not be made" under the guidelines.

Lilly is not appropriately applied here. *Lilly* concerned a University of California patent disclosing the isolation and sequencing of rat insulin cDNA, and the issue of whether this disclosure provided adequate support for claims generically reciting vertebrate insulin cDNA and mammalian insulin cDNA. (*Lilly,* 43 USPQ2d at 1404-1405.) The patentee disclosed only a process for obtaining human insulin-encoding cDNA or other mammalian insulin cDNAs other than rat. (*Lilly,* 43 USPQ2d at 1405.) The patentee had not disclosed the structure of human insulin cDNA but only a plan for obtaining it. In contrast, the present claims 1, 2, and 21 recite the precise structure of CA125 (SEQ ID NO:5). This also, with knowledge of the genetic code, inherently

discloses the structure of every nucleic acid encoding SEQ ID NO:5 or a fragment thereof.

Furthermore, although in this case every species within the scope of claim 1 is described, the court in Lilly, stated: "[E]very species in a genus need not be described in order that a genus meet the written description requirement." *Lilly,* 43 USPQ2d at 1405.

In view of the amendments and remarks herein, withdrawal of the rejection of claims 3 and 4 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

The Rejection of the Claims Under 35 U.S.C. § 102

Claims 1 and 2 were rejected under 35 U.S.C. 102(a) as being anticipated by O'Brien et al. (*Tumor Biology*, 2002, May-June; 23:154-169). This rejection is respectfully traversed.

The authors of the cited *Tumor Biology* paper were the applicants – Timothy O'Brien, John Beard, and Lowell Underwood – along with Kazushi Shigemasa. With this response Applicants are submitting a Katz Declaration under 37 C.F.R. § 1.132 (*In re Katz*, 687 F.2d 450, 215 U.S.P.Q. 14 (CCPA 1982); M.P.E.P. § 2132.01). In the Declaration, Drs. O'Brien, Beard, and Underwood declare that Kazushi Shigemasa was a fellow working in their laboratory who performed some experiments analyzing the biological role of CA125 in cancer. They declare that he did not have a significant role in cloning and sequencing CA125 nucleic acids. They declare that although Kazushi Shigemasa is a coauthor of the cited paper, he is not a co-inventor of the subject matter disclosed therein.

Under the rule of *In re Katz* and under M.P.E.P. 2132.01, this Declaration establishes that Dr. Shigemasa is not an inventor and that the cited O'Brien et al. paper discloses the work of the Applicants. Since the cited O'Brien et al. paper discloses the work of the Applicants, it is not the work of "another" and is therefore not prior art under 35 U.S.C. § 102(a) (*In re Katz, supra*; M.P.E.P. § 2132.01).

In view of these remarks and the enclosed Katz Declaration under 37 C.F.R. § 1.132, Applicants respectfully request withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. § 102(a) as being anticipated by O'Brien et al. (*Tumor Biology*, 2002, May-June; 23:154-169).

Claim 3 was rejected under 35 U.S.C. § 102(b) as being anticipated by O'Brien et al. (*Tumor Biology*, 2002, May-June; 23:154-169). Claim 3 is canceled herein, obviating this rejection.

Claims 3 and 4 were rejected under 35 U.S.C. § 102(b) as being anticipated by NCI-CGAP (GenBank Accession No. AA640762, October 28, 1997). This rejection, insofar as it may apply to the amended claims, is respectfully traversed.

Claims 3 and 4 are canceled. Claims 1 and 2 recite an isolated nucleic acid molecule encoding CA125 (SEQ ID NO:5) or a fragment thereof, wherein the isolated nucleic acid molecule encodes a polypeptide comprising residues 1-10,427 of SEQ ID NO:5 or a fragment of residues 1-10,427 of SEQ ID NO:5 recognized by an antibody that selectively binds to SEQ ID NO:5. GenBank accession no. AA640762 discloses a 361-nucleotide sequence that is an exact match for a fragment of SEQ ID NO:4 beginning at nucleotide 63,858. This encodes a segment of SEQ ID NO:5 beginning at amino acid residue 21,219 in the multiple repeat domain. The accession number AA640762 sequence is also homologous, although not an exact match, with several other sequences within the coding region for the multiple repeat domain.

But the amended claim 1 recites an isolated nucleic acid molecule encoding CA125 (SEQ ID NO:5) or a fragment thereof, wherein the isolated nucleic acid molecule encodes a polypeptide comprising residues 1-10,427 of SEQ ID NO:5 or a fragment of residues 1-10,427 of SEQ ID NO:5 recognized by an antibody that selectively binds to SEQ ID NO:5 (emphasis added). Residues 1-10,427 of SEQ ID NO:5 is the amino terminal extension of CA125 that is newly presented in this patent application. The sequence of accession number AA640762 is not found in the genomic or cDNA sequences encoding residues 1-10,427 of SEQ ID NO:5. Accordingly, accession no. AA640762 does not disclose a nucleic acid molecule that encodes a fragment of residues 1-10,427 of SEQ ID NO:5, as is recited in claims 1, 2, and 21, and therefore it does not anticipate any of claims 1, 2, and 21.

In view of these remarks and the amendments to the claims, Applicants respectfully request withdrawal of the rejection of claims 3 and 4 under 35 U.S.C. § 102(b) as being anticipated by NCI-CGAP (GenBank Accession No. AA640762, October 28, 1997).

Double Patenting

Claims 2-4 were provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 25-27 of copending application no. 10/475,117. This rejection is provisional, and Applicant will address it upon allowance of claims in either application.

Conclusion

The Examiner is invited to telephone Applicant's attorney (651-207-8270) to facilitate prosecution of this application.

Respectfully submitted,

TIMOTHY O'BRIEN ET AL.

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient first class postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this day November 14, 2006.

Hugh McTavish